



PATENT
Attorney Docket No.: CAL1110-4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Lin et al. Art Unit: 1755
Application No.: 10/607,023 Examiner: C.M. Koslow
Filed: June 27, 2003 Confirmation No.: 5563
Title: TETRACALCIUM PHOSPHATE (TTCP) HAVING CALCIUM
PHOSPHATE WHISKER ON SURFACE

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF CHIEN-PING JU
UNDER 35 U.S.C. §1.132

Sir:

I, Dr. Chien-Ping Ju, do hereby declare and state that:

1. I am presently a member of the faculty in the Department of Materials Science at National Cheng Kung University located at No. 1, Ta-Hsueh Road, Tainan, Taiwan.
2. I hold a PhD in Materials Science and Engineering granted by Marquette University in 1981.
3. I am also a named inventor of the above- identified application, including the calcium phosphate cements and methods for making them disclosed in the application.
4. Experiments have been conducted under my supervision and control in the laboratories of The Cana Lab Corporation at Taipei, Taiwan, to illustrate the differences between the compositions and properties of the invention CPCs as described in Examples 5, 6 and 7 of the present application and the prior art compositions as prepared according to the disclosure in Examples 1, 4 and 5 of the Ison patent.

5. CPCs prepared from the invention whisker-grown particles is represented in Examples 5, 6, and 7 of the present application. For comparison CPC prior art pastes were made and formed according to the methods described in Example 1, Example 4 and Example 5 of the Ison patent. The prior art CPCs were examined microscopically to seek evidence that fine crystals formed on the surface. No such evidence was found.

One minute after mixing, samples of each of the prior art CPCs were packed under pressure of 0.7 Mpa for 5 min in a 6 mm diameter and 12 mm deep cylindrical mold. The sample was then removed from the mold and allowed to set before conducting compressive strength testing. The compressive strength was measured using a desk-top mechanical tester (Shimadzu AGS-500D, Tokyo, Japan) at a crosshead speed of 1.0 mm/min. Results of the compression strength tests are summarized in attached Exhibit 1. The compression strengths of 2.4, 0.4 and 0.5 Mpa, respectively, were recorded for the prior art CPCs of Example 1, Example 4 and Example 5 of the Ison patent.

6. To study the effect of immersion on compressive strength, the prior art CPC samples were immersed in Hanks' physiological solution that was maintained at 37 °C and agitated to help maintain uniform ion concentration. During immersion the cylinders were photographed at 0, 5, 10, 15 and 20 sec intervals to record the degree of dissolution of the cylinders. The results of these tests are shown in the series of photographs in attached Exhibits 2 – 4. In each case, as can be seen by visual inspection of the photographs in Exhibits 2 – 4, prior art samples all suffered substantial dissolution within 20 seconds of immersion, indicating that the prior art cements would not increase in compressive strength after immersion in Hank's solution. By contrast, the Specification teaches that in each case the invention CPC actually increased in compressive strength after soaking in Hank's solution for up to one day.

Thus, these experiments show that neither the composition nor the properties of the invention CPC as described in Examples 5, 6 and 7 of the Specification are similar to those described in Examples 1, 4 and 5 of the Ison patent.

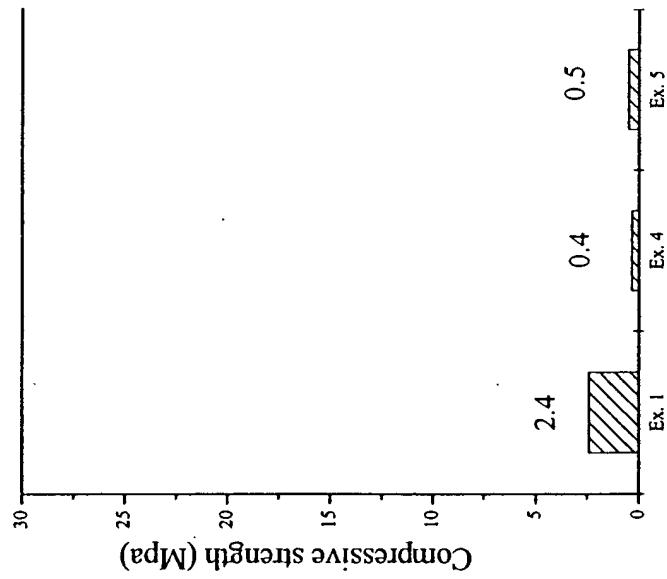
7. I further declare that all statements made herein of knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

10/26/2004
Date

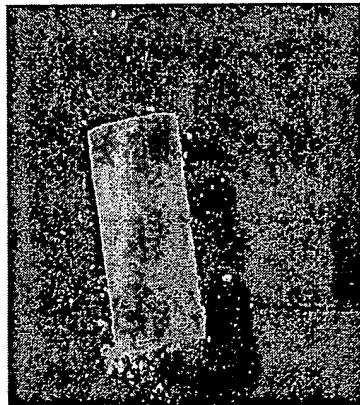

Dr. Chien-Ping Ju

Attachments
Exhibits 1-4.

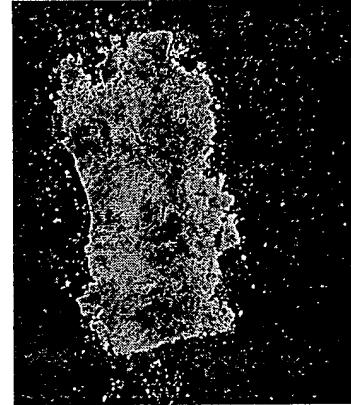
Compressive Strength



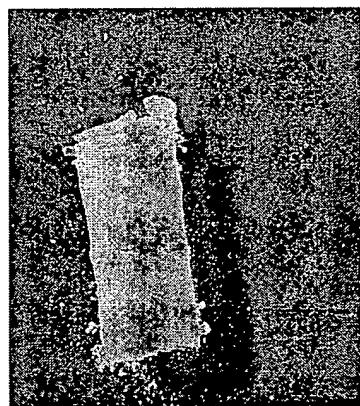
Sample on left : Ex.1 of '399
Sample on right : Our CPC



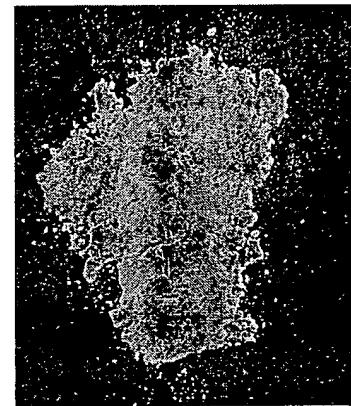
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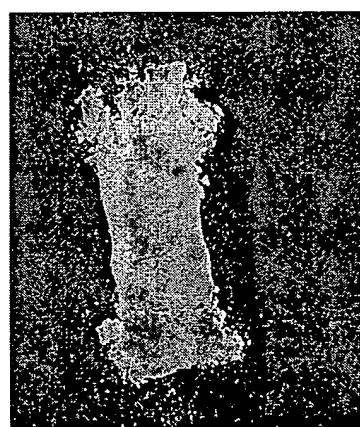
15sec



5sec



20sec



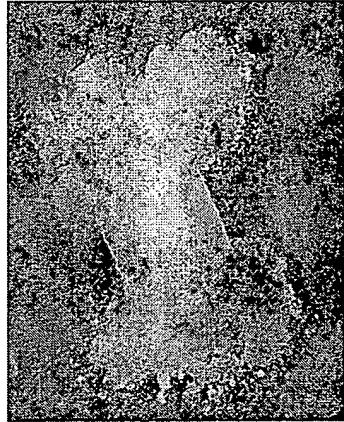
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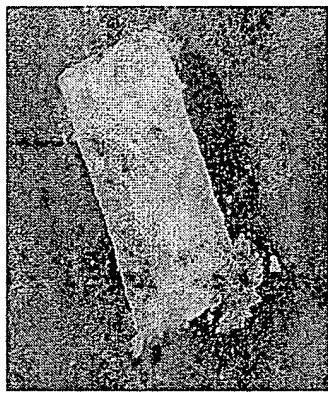
Sample on left : Ex.4 of '399
Sample on right : Our CPC



0sec



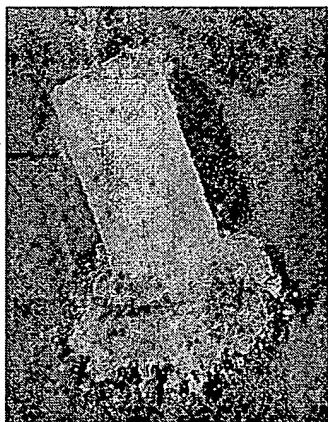
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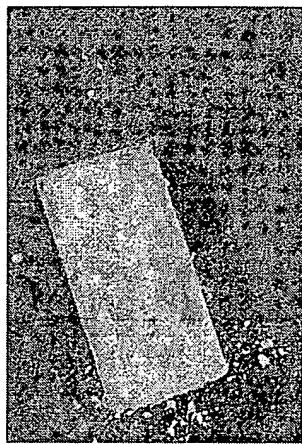
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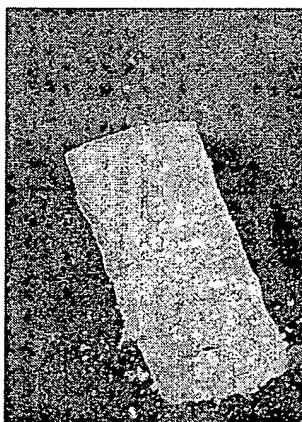
Sample on left : Ex.5 of '399
Sample on right : Our CPC



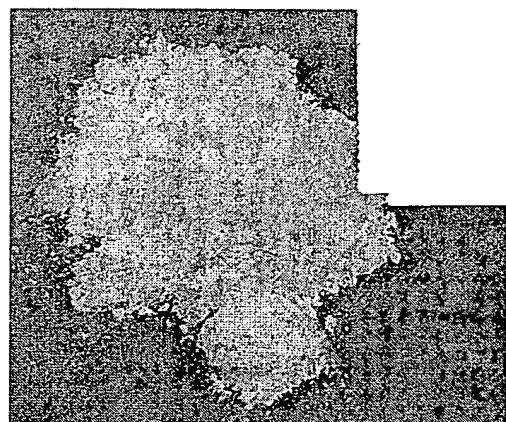
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